

- 442.154 Cefpodoxime proxetil oral dosage forms.
- 442.154a Cefpodoxime proxetil tablets.
- 442.154b Cefpodoxime proxetil granules for oral suspension.
- 442.180 Cefprozil oral dosage forms.
- 442.180a Cefprozil tablets.
- 442.180b Cefprozil for oral suspension.

Subpart C—Injectable Dosage Forms

- 442.208 Cefamandole nafate for injection.
- 442.209 Cefamandole sodium for injection.
- 442.211 Cefazolin sodium injectable dosage forms.
- 442.211a Sterile cefazolin sodium.
- 442.211b Cefazolin sodium injection.
- 442.212 Cefoperazone injectable dosage forms.
- 442.212a Sterile cefoperazone sodium.
- 442.212b Cefoperazone sodium injection.
- 442.213 Cefotaxime injectable dosage forms.
- 442.213a Sterile cefotaxime sodium.
- 442.213b Cefotaxime sodium injection.
- 442.214 Cefoxitin injectable dosage forms.
- 442.214a Sterile cefoxitin sodium.
- 442.214b Cefoxitin sodium injection.
- 442.216 Ceftazidime injectable dosage forms.
- 442.216a Ceftazidime pentahydrate for injection.
- 442.216b Ceftazidime sodium injection.
- 442.217 Ceftizoxime injectable dosage forms.
- 442.217a Sterile ceftizoxime sodium.
- 442.217b Ceftizoxime sodium injection.
- 442.218 Cefuroxime injectable dosage forms.
- 442.218a Sterile cefuroxime sodium.
- 442.218b Cefuroxime sodium injection.
- 442.220 Sterile cefonicid sodium.
- 442.222 Cefmenoxime hydrochloride for injection.
- 442.223 Sterile cephaloridine.
- 442.225 Cephalothin sodium injectable dosage forms.
- 442.225a Sterile sodium cephalothin.
- 442.225b Cephalothin sodium injection.
- 442.225c Cephalothin sodium for injection.
- 442.229 Sterile cephradine sodium.
- 442.240 Cephradine injectable dosage forms.
- 442.240a Cephradine for injection.
- 442.240b Sterile cephradine.
- 442.250 Ceforanide for injection.
- 442.253 Cefotetan injectable dosage forms.
- 442.253a Sterile cefotetan disodium.
- 442.253b Cefotetan sodium injection.
- 442.255 Ceftriaxone injectable dosage forms.
- 442.255a Sterile ceftriaxone sodium.
- 442.255b Ceftriaxone sodium injection.
- 442.258 Cefotiam dihydrochloride for injection.
- 442.260 Cefpiramide sodium for injection.
- 442.270 Cefmetazole injectable dosage forms.
- 442.270a Sterile cefmetazole sodium.
- 442.270b Cefmetazole sodium injection.

AUTHORITY: 21 U.S.C. 357.

SOURCE: 39 FR 19040, May 30, 1974, unless otherwise noted.

Subpart A—Bulk Drugs

§ 442.4 Cefaclor monohydrate.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Cefaclor monohydrate is the monohydrate form of (6*R*, 7*R*)-7-[(*R*)-2-amino-2-phenylacetamido]-3-chloro-8-oxo-5-thia-1-azabicyclo [4.2.0]oct-2-ene-2-carboxylic acid. It is so purified and dried that:

- (i) Its potency is not less than 860 micrograms and not more than 1,050 micrograms of cefaclor per milligram on an “as is” basis.
- (ii) Its moisture content is not less than 3.0 percent and not more than 8.0 percent.
- (iii) Its pH in an aqueous suspension containing 25 milligrams per milliliter is not less than 3.0 and not more than 4.5.

(iv) It gives a positive identity test.

(v) It is crystalline.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, moisture, pH, identity, and crystallinity.

(ii) Samples required: 10 packages, each containing approximately 300 milligrams.

(b) *Tests and methods of assay—(1) Potency.* Use either of the following methods; however, the results obtained from the hydroxylamine colorimetric assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample in sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to obtain a stock solution containing 1 milligram of cefaclor per milliliter (estimated). Further dilute an aliquot of the stock solution with solution 1 to the reference concentration of 5.0 micrograms of cefaclor per milliliter (estimated).

(ii) *Hydroxylamine colorimetric assay.* Proceed as directed in § 442.40(b)(1)(ii) of this chapter, except prepare the working standard and sample solutions

and calculate the cefaclor content as follows:

(a) *Preparation of working standard solution.* Dissolve and dilute an accurately weighed portion of the cefaclor working standard in sufficient 0.1M potassium phosphate buffer, pH 4.5 (as described in §436.101(a)(4) of this chapter) to obtain a concentration of 1 milligram of cefaclor per milliliter.

(b) *Preparation of sample solution.* Dissolve an accurately weighed portion of the sample in sufficient 0.1M potassium phosphate buffer, pH 4.5 (as described in §436.101(a)(4) of this chapter) to obtain a concentration of 1 milligram of cefaclor per milliliter.

(c) *Calculations.* Calculate the cefaclor content in micrograms per milligram as follows:

$$\frac{\text{Micrograms of cefaclor per milligram of sample}}{A_s \times W_u} = \frac{A_u \times P_a}{A_s \times W_u}$$

where:

A_u = Absorbance of sample solution;

P_a = Potency of working standard solution in micrograms per milliliter;

A_s = Absorbance of working standard solution;

W_u = Milligrams of sample per milliliter of sample solution.

(2) *Moisture.* Proceed as directed in §436.201 of this chapter.

(3) *pH.* Proceed as directed in §436.202 of this chapter, using an aqueous suspension containing 25 milligrams per milliliter.

(4) *Identity.* Proceed as directed in §436.211 of this chapter, using the sample preparation described in paragraph (b)(2) of that section.

(5) *Crystallinity.* Proceed as directed in §436.203(a) of this chapter.

[46 FR 3832, Jan. 16, 1981]

§ 442.6 Cefadroxil monohydrate.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Cefadroxil monohydrate is 7-[D-2-amino-2(p-hydroxy-phenyl)acetamido] - 3 - methyl - 8 - oxo- 5-thia-1-azabicyclo[4.2.0] oct-2-ene-2-carboxylic acid monohydrate. It is so purified and dried that:

(i) Its potency is not less than 900 micrograms and not more than 1,050

micrograms of cefadroxil per milligram on an anhydrous basis.

(ii) [Reserved]

(iii) Its moisture content is not less than 4.2 percent and not more than 6.0 percent.

(iv) Its pH in an aqueous solution containing 50 milligrams per milliliter is not less than 4.0 and not more than 6.0.

(v) When calculated on an anhydrous basis, its absorptivity at 264 nanometers is not less than 95 percent and not more than 104 percent of that of the cefadroxil standard similarly treated and corrected for potency.

(vi) It passes the identity test.

(vii) It is crystalline.

(2) *Labeling.* It shall be labeled in accordance with the requirements of §432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, moisture, pH, absorptivity, identity, and crystallinity.

(ii) Samples required: 10 packages, each containing approximately 500 milligrams.

(b) *Tests and methods of assay—(1) Potency.* Use either of the following methods; however, the results obtained from the hydroxylamine colorimetric assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in §436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample in sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Further dilute an aliquot of the stock solution with solution 1 to the reference concentration of 20 micrograms of cefadroxil per milliliter (estimated).

(ii) *Hydroxylamine colorimetric assay for cefadroxil.* Proceed as directed in §442.40(b)(1)(ii) of this chapter, except prepare the working standard and sample solutions and calculate the potency of the sample as follows:

(a) *Preparation of working standard solutions.* Dissolve and dilute an accurately weighed portion of the cefadroxil working standard in sufficient distilled water to obtain a stock